K002741 JUL 3 2002

510(k) SUMMARY

Albert Browne Ltd.

Browne TST Dual Use Test Pack

1. SUBMITTER NAME AND ADDRESS

Mr. Alan Charlton
Albert Browne Ltd.
190 Waterside Road
Hamilton Industrial Park
Leicester LE5 1QZ
United Kingdom

DATE PREPARED: June 26, 2002

2. DEVICE NAME

Proprietary Name:	Browne TST Dual Use Test Pack
Common/Usual Name:	Chemical indicator
Classification Name:	Physical/chemical sterilization process indicator

3. PREDICATE DEVICES

- TST Control Integrator for Steam Autoclave (K965154)
- Propper PASS/FAIL Challenge Pack (K991276)
- 3M Comply Sterigage Steam Chemical Integrator Test Pack (K952408)

4. INTENDED USE

The Browne TST Dual Use Test Pack is a chemical sterilization process monitor that can be used as either:

- **Bowie Dick Test** – in an empty chamber to monitor air removal and steam penetration during the vacuum stage of 132°C (270°F), 134°C (273°F), and 135°C (275°F) test cycles
- **Challenge Pack** – in a loaded chamber to monitor steam penetration during the hold/plateau stage of 132°C (270°F), 134°C (273°F), and 135°C (275°F) steam

sterilization cycles.

5. DEVICE DESCRIPTION

The proposed Dual Use Test Pack consists of a chemical integrator surrounded by a steam penetration barrier. The indicator ink used for the proposed Dual Use Test Pack integrator is identical to the ink used for the TST Control Integrator for Steam Autoclave (K965154).

6. TECHNOLOGICAL CHARACTERISTICS

The proposed and predicate devices indicate exposure to steam sterilization cycle parameters through a visible color change in a chemical integrator. The integrators change color due to a chemical interaction in the indicator ink that occurs when the integrator is exposed to steam at 132°C (270°F), 134°C (273°F), and 135°C (275°F) for 3-4 minutes.

7. PERFORMANCE TESTING

Data was provided to demonstrate the following:

- When used in an empty chamber as a Bowie Dick Test Pack, the Dual Use Test Pack has sufficient sensitivity to detect a 2°C temperature depression in test cycles of 3-4 minutes hold time at 132°C (270°F), 134°C (273°F), and 135°C (275°F).
- When used in a loaded chamber as a process challenge device in sterilization cycles at 132°C (270°F), 134°C (273°F), and 135°C (275°F), the Dual Use Test Pack provides a greater challenge to the sterilization cycle than the integrator alone.
- The Dual Use Test Pack continues to perform as designed three years after the date of manufacture.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 2002

Albert Browne Limited
C/O Ms. Cythia J. M. Nolte
Medical Device Consultants
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K002741
Trade/Device Name: Browne TST Dual Use Test Pack
Regulation Number: 880.2800
Regulation Name: Chemical Indicator
Regulatory Class: II
Product Code: JOJ
Dated: April 23, 2002
Received: April 24, 2002

Dear Ms. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002741
Device Name: Browne TST Dual Use Test Pack

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002741

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)